

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

PATRICIA ARMENDO, et al.,)	
)	
Plaintiffs,)	
)	Civil Action No.: 04-12494-DPW
vs.)	
)	ANSWER AND JURY CLAIM OF
SMITHKLINE BEECHAM)	SMITHKLINE BEECHAM
CORPORATION D/B/A)	CORPORATION d/b/a
GLAXOSMITHKLINE, et al.,)	GLAXOSMITHKLINE
)	
Defendants.)	

Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") by and through its undersigned counsel, hereby responds to Plaintiffs' Complaint (Plaintiffs' Complaint), as follows:

I. Introduction

1. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' usage of Paxil® ("Paxil") and alleged injuries described in Paragraph 1 of Plaintiffs' Complaint. GSK admits that the prescription medication paroxetine hydrochloride is sold under the trade name Paxil. GSK further admits that it marketed, advertised, and distributed Paxil in the State of Massachusetts. Except as so admitted, GSK denies all remaining allegations in Paragraph 1 of Plaintiffs' Complaint.

II. The Parties

2. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of Plaintiffs' Complaint.

3. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of Plaintiffs' Complaint.

4. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of Plaintiffs' Complaint.

5. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of Plaintiffs' Complaint.

6. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of Plaintiffs' Complaint.

7. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of Plaintiffs' Complaint.

8. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of Plaintiffs' Complaint.

9. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of Plaintiffs' Complaint.

10. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of Plaintiffs' Complaint.

11. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of Plaintiffs' Complaint.

12. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of Plaintiffs' Complaint.

13. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of Plaintiffs' Complaint.

14. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of Plaintiffs' Complaint.

15. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 15 of Plaintiffs' Complaint.

16. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of Plaintiffs' Complaint.

17. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17 of Plaintiffs' Complaint.

18. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of Plaintiffs' Complaint.

19. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of Plaintiffs' Complaint.

20. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of Plaintiffs' Complaint.

21. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 of Plaintiffs' Complaint.

22. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of Plaintiffs' Complaint.

23. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of Plaintiffs' Complaint.

24. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of Plaintiffs' Complaint.

25. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 of Plaintiffs' Complaint.

26. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of Plaintiffs' Complaint.

27. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of Plaintiffs' Complaint.

28. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of Plaintiffs' Complaint.

29. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of Plaintiffs' Complaint.

30. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of Plaintiffs' Complaint.

31. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of Plaintiffs' Complaint.

32. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 of Plaintiffs' Complaint.

33. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 of Plaintiffs' Complaint.

34. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 of Plaintiffs' Complaint.

35. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of Plaintiffs' Complaint.

36. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 of Plaintiffs' Complaint.

37. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of Plaintiffs' Complaint.

38. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 of Plaintiffs' Complaint.

39. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 of Plaintiffs' Complaint.

40. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of Plaintiffs' Complaint.

41. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of Plaintiffs' Complaint.

42. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of Plaintiffs' Complaint.

43. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of Plaintiffs' Complaint.

44. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of Plaintiffs' Complaint.

45. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of Plaintiffs' Complaint.

46. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of Plaintiffs' Complaint.

47. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' states of residence, usage of Paxil, or alleged injuries described in Paragraph 47 of Plaintiffs' Complaint. GSK denies that

Paxil caused injuries or symptoms as alleged in Plaintiffs' Complaint and denies the remaining allegations in Paragraph 47 of Plaintiffs' Complaint.

48. GSK admits that it is a Pennsylvania corporation operating under the name SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and with its principal place of business in the Commonwealth of Pennsylvania. GSK also admits that it has marketed, promoted, advertised and distributed Paxil in the State of Massachusetts and, for purposes of this litigation, admits that it has manufactured Paxil. Except as so admitted, GSK denies any remaining allegations in Paragraph 48 of Plaintiffs' Complaint.

49. GSK admits only that GlaxoSmithKline, plc ("PLC") is a public limited company incorporated in the United Kingdom. Except as so admitted, GSK denies the remaining allegations in Paragraph 49 of Plaintiffs' Complaint.

III. Nature of the Case

50. Paragraph 50 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK denies that Plaintiffs are properly joined in this lawsuit. GSK is without knowledge or information sufficient to form a belief as to the truth of all remaining allegations in Paragraph 50 of Plaintiffs' Complaint.

51. GSK denies the allegations in Paragraph 51 of Plaintiffs' Complaint.

52. GSK denies the allegations in Paragraph 52 of Plaintiffs' Complaint

IV. Jurisdictional Allegations

53. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' residence. GSK admits that it is a Pennsylvania corporation with its principal place of business in the Commonwealth of

Pennsylvania. GSK denies any remaining allegations in Paragraph 53 of Plaintiff's Complaint.

54. GSK admits that this federal court has jurisdiction over this case. GSK further admits that Plaintiffs purport to seek damages in excess of \$75,000. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 of Plaintiffs' Complaint.

55. GSK denies that venue in this district or division is proper as to some or all of the named Plaintiffs, and denies any remaining allegations in Paragraph 55 of Plaintiffs' Complaint.

V. Factual Allegations

56. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' Paxil usage as described in Paragraph 56 of Plaintiffs' Complaint. GSK denies that Paxil caused injuries or symptoms as alleged in Plaintiffs' Complaint and denies any remaining allegations in Paragraph 56 of Plaintiffs' Complaint.

57. Paragraph 57 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK admits only that the federal laws and regulations governing pharmaceutical products and GSK's obligations with respect to such products speak for themselves. Except as so admitted, GSK denies the remaining allegations in Paragraph 57 of Plaintiffs' Complaint.

58. GSK admits in response to the allegations of Paragraph 58 of Plaintiffs' Complaint only that Paxil was approved as a prescription medication in the United States

for the indication of depression on December 29, 1992; that Paxil is an antidepressant; that Paxil is generally classified as a selective serotonin reuptake inhibitor (“SSRI”); and that Prozac and Zoloft are generally referred to as SSRIs. GSK denies any remaining allegations in Paragraph 58 of Plaintiffs’ Complaint.

59. GSK admits in response to the allegations of Paragraph 59 of Plaintiffs’ Complaint only that it has made certain statements about Paxil, the terms of which speak for themselves. GSK denies all remaining allegations in Paragraph 59 of Plaintiffs’ Complaint.

60. GSK admits in response to the allegations of Paragraph 60 of Plaintiffs’ Complaint only that Paxil is sold under the name Seroxat® (“Seroxat”) in certain foreign countries. GSK also admits that any labeling for Paxil as it is distributed in foreign countries speaks for itself, and that such labeling is developed and distributed in conjunction with those foreign countries’ respective regulatory authorities. GSK denies all remaining allegations in Paragraph 60 of Plaintiffs’ Complaint.

61. GSK denies the allegations in Paragraph 61 of Plaintiffs’ Complaint.

62. GSK is without knowledge or information to form a belief as to the truth of the allegations concerning Plaintiffs’ medical treatment. GSK denies that Paxil caused Plaintiffs’ alleged injuries and denies any remaining allegations in Paragraph 62 of Plaintiffs’ Complaint.

63. GSK states in response to the allegations of Paragraph 64 of Plaintiffs’ Complaint that the World Health Organization data referenced in Paragraph 63 of Plaintiffs’ Complaint speaks for itself. GSK denies the allegations in Paragraph 63 of Plaintiffs’ Complaint.

64. GSK admits in response to the allegations of Paragraph 64 of Plaintiffs' Complaint only that Paxil has a "half life" and that Paxil is generally classified as an SSRI. Further responding, GSK states that the survey cited in Paragraph 64 of Plaintiffs' Complaint speaks for itself. GSK denies the allegations in Paragraph 64 of Plaintiffs' Complaint.

65. GSK states in response to the allegations of Paragraph 65 of Plaintiffs' Complaint that the study cited in Paragraph 65 speaks for itself. GSK denies the allegations in Paragraph 65 of Plaintiffs' Complaint.

66. Paragraph 66 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK admits that the Food and Drug Administration ("FDA") has approved the label for Paxil and that its label has been revised over time, including in December 2001. Further responding, GSK states that Paxil's labeling speaks for itself, and that the federal laws and regulations governing pharmaceutical products and GSK's obligations with respect to such products speak for themselves. GSK denies the remaining allegations in Paragraph 66 of Plaintiffs' Complaint.

67. GSK states in response to the allegations of Paragraph 65 of Plaintiffs' Complaint that Paxil's labeling speaks for itself. GSK denies the remaining allegations in Paragraph 67 of Plaintiffs' Complaint.

68. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' Paxil usage as described in Paragraph 68 of Plaintiffs' Complaint. GSK admits only that it has published information about Paxil and states that such information speaks for itself. GSK further states that Paxil's

labeling speaks for itself. GSK denies the remaining allegations in Paragraph 68 of Plaintiffs' Complaint.

69. GSK admits in response to the allegations of Paragraph 69 of Plaintiffs' Complaint only that it has published information about Paxil and states that such information speaks for itself. GSK further states that Paxil's labeling speaks for itself. GSK denies the remaining allegations in Paragraph 69 of Plaintiffs' Complaint.

70. GSK states in response to the allegations of Paragraph 70 of Plaintiffs' Complaint only that the report cited in Paragraph 70 speaks for itself. GSK denies the remaining allegations in Paragraph 70 of Plaintiffs' Complaint.

71. GSK denies the allegations in Paragraph 71 of Plaintiffs' Complaint.

72. GSK admits in response to the allegations of Paragraph 72 of Plaintiffs' Complaint that Paxil has a "half life" and that it has published information about Paxil. Further responding, GSK states that such information speaks for itself. GSK denies the remaining allegations in Paragraph 72 of Plaintiffs' Complaint.

73. GSK denies the allegations in Paragraph 73 of Plaintiffs' Complaint.

COUNT I

74. In response to Paragraph 74 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

75. Paragraph 78 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK states that M.G.L. ch. 93A, § 2 and 9 speak for themselves. GSK denies the

remaining allegations in Paragraph 75, including sub-paragraphs (a) through (d), of Plaintiffs' Complaint.

76. Paragraph 76 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK denies the allegations in Paragraph 76, including sub-paragraphs (a) through (l), of Plaintiffs' Complaint.

77. GSK denies the allegations in Paragraph 77 of Plaintiffs' Complaint.

78. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' alleged usage of Paxil and alleged injuries as described in Paragraph 78 of Plaintiffs' Complaint. GSK denies the remaining allegations in Paragraph 78 of Plaintiffs' Complaint, including the "WHEREFORE" Paragraph following Paragraph 78 of Plaintiffs' Complaint.

COUNT II

79. In response to Paragraph 79 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

80. GSK denies the allegations in Paragraph 80, including subparagraphs (a) through (l), of Plaintiffs' Complaint.

81. GSK denies the allegations in Paragraph 81 of Plaintiffs' Complaint.

82. GSK denies the allegations in Paragraph 82 of Plaintiffs' Complaint.

83. GSK denies the allegations in Paragraph 83 of Plaintiffs' Complaint.

84. GSK denies the allegations in Paragraph 84 of Plaintiffs' Complaint.

85. GSK denies the allegations in Paragraph 85 of Plaintiffs' Complaint.

86. GSK admits in response to the allegations of Paragraph 86 of Plaintiffs' Complaint only that it has marketed, promoted, advertised and distributed Paxil in the State of Massachusetts and, for purposes of this litigation, admits that it has manufactured Paxil. GSK denies the remaining allegations in Paragraph 86 of Plaintiffs' Complaint.

87. GSK denies the allegations in Paragraph 87, including the "WHEREFORE" Paragraph following Paragraph 87 of Plaintiffs' Complaint.

COUNT III

88. In response to Paragraph 88 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

89. Paragraph 89 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK denies that it breached any duty. GSK is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 89 of Plaintiffs' Complaint.

90. Paragraph 90 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK denies that it breached any duty. GSK is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 90 of Plaintiffs' Complaint.

91. GSK denies the allegations in Paragraph 91, including the "WHEREFORE" Paragraph following Paragraph 91 of Plaintiffs' Complaint.

COUNT IV

92. In response to Paragraph 92 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

93. GSK states in response to the allegations of Paragraph 93 of Plaintiffs' Complaint that the FDA-approved prescribing information for Paxil and GSK's promotional materials for Paxil speak for themselves. GSK denies the allegations in Paragraph 93 of Plaintiffs' Complaint.

94. GSK states in response to the allegations of Paragraph 94 of Plaintiffs' Complaint only that the FDA-approved prescribing information for Paxil and GSK's promotional materials for Paxil speak for themselves. GSK denies the remaining allegations in Paragraph 94 of Plaintiffs' Complaint.

95. GSK denies the allegations in Paragraph 95 of Plaintiffs' Complaint.

96. GSK denies the allegations in Paragraph 96 of Plaintiffs' Complaint.

97. GSK denies the allegations in Paragraph 97, including the "WHEREFORE" Paragraph following Paragraph 97 of Plaintiffs' Complaint.

COUNT V

98. In response to Paragraph 98 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

99. GSK states in response to the allegations of Paragraph 99 of Plaintiffs' Complaint that the FDA-approved label for Paxil speaks for itself. GSK denies the remaining allegations in Paragraph 99 of Plaintiffs' Complaint.

100. GSK denies the allegations in Paragraph 100, including the “WHEREFORE” Paragraph following Paragraph 100 of Plaintiffs’ Complaint.

COUNT VI

101. In response to Paragraph 101 of Plaintiffs’ Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

102. Paragraph 102 contains legal conclusions which do not require a response from GSK. To the extent this Paragraph contains factual allegations directed at GSK, GSK denies that it breached any duty, and any remaining allegations in Paragraph 102 of Plaintiffs’ Complaint.

103. GSK denies the allegations in Paragraph 103, including the “WHEREFORE” Paragraph following Paragraph 103 of Plaintiffs’ Complaint.

COUNT VII

104. In response to Paragraph 104 of Plaintiffs’ Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

105. GSK denies the allegations in Paragraph 105 of Plaintiffs’ Complaint.

106. GSK denies the allegations in Paragraph 106 of Plaintiffs’ Complaint.

107. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs’ Paxil usage as described in Paragraph 107 of Plaintiffs’ Complaint. GSK denies any remaining allegations in Paragraph 107 of Plaintiffs’ Complaint.

108. GSK denies the allegations in Paragraph 108 of Plaintiffs’ Complaint.

109. GSK admits in response to the allegations of Paragraph 109 of Plaintiffs' Complaint that it promoted Paxil. GSK denies the remaining allegations in Paragraph 109 of Plaintiffs' Complaint.

110. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' Paxil usage as described in Paragraph 110 of Plaintiffs' Complaint. GSK denies that Paxil caused Plaintiffs' injuries, and denies the remaining allegations in Paragraph 110 of Plaintiffs' Complaint.

111. GSK denies the allegations in Paragraph 111, including the "WHEREFORE" Paragraph following Paragraph 111 of Plaintiffs' Complaint.

COUNT VIII

112. In response to Paragraph 112 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

113. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' Paxil usage as described in Paragraph 113 of Plaintiffs' Complaint. GSK denies the remaining allegations in Paragraph 113 of Plaintiffs' Complaint, including subparagraphs (a) through (d).

114. GSK denies the allegations in Paragraph 114 of Plaintiffs' Complaint.

115. GSK denies the allegations in Paragraph 115 of Plaintiffs' Complaint.

116. GSK denies the allegations in Paragraph 116, including the "WHEREFORE" Paragraph following Paragraph 116 of Plaintiffs' Complaint.

COUNT VIII

117. In response to Paragraph 117 of Plaintiffs' Complaint, GSK incorporates by reference all preceding and subsequent Paragraphs in this Answer and each and every one of its defenses.

118. GSK denies the allegations in Paragraph 118 of Plaintiffs' Complaint.

119. GSK denies the allegations in Paragraph 119 of Plaintiffs' Complaint.

120. GSK denies the allegations in Paragraph 120 of Plaintiffs' Complaint.

121. GSK denies the allegations in Paragraph 121, including the "WHEREFORE" Paragraph following Paragraph 121 of Plaintiffs' Complaint.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

Plaintiffs' Complaint fails, in whole or in part, to state a cause of action upon which relief may be granted.

SECOND DEFENSE

Plaintiffs' claims are preempted or barred, in whole or in part, by the federal Food, Drug and Cosmetic Act, as amended, including but limited to, the doctrine of primary jurisdiction because the Food and Drug Administration of the United States Department of Health and Human Services has primary jurisdiction over the issues raised in Plaintiffs' Complaint and exclusive regulatory control of products such as the product at issue here. The grant of the relief prayed for in Plaintiffs' Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Article VI, Clause 2) of the United States Constitution and the Court

should either dismiss these claims for relief or defer consideration of them to the Food and Drug Administration.

THIRD DEFENSE

Plaintiffs' Complaint fails to state a claim against GSK because there is no private right of action under the Federal Food, Drug and Cosmetic Act as amended.

FOURTH DEFENSE

Venue may be improper or dismissible as to all or some of these Plaintiffs on the grounds of forum *non conveniens*. If so, Plaintiffs' Complaint should be dismissed or transferred to the appropriate venue.

FIFTH DEFENSE

All Plaintiffs but Plaintiff Patricia Armendo must be dismissed from this action under Fed. R. Civ. P. 21 for misjoinder, or each Plaintiff's claims severed, or separate trials ordered.

SIXTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

SEVENTH DEFENSE

Plaintiffs' claims relating to alleged communications between GSK and regulatory agencies of the United States government or any other government are barred in whole or in part by operation of applicable law, including the First Amendment rights of GSK to petition the government. *See, e.g., Eastern Railroad Presidents Conference v. Noer Motor Freight, Inc.*, 365 U.S. 127 (1961).

EIGHTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the commercial speech of GSK relating to Paxil is not false or misleading and is protected under the First Amendment to the United States Constitution and under the Massachusetts Constitution.

NINTH DEFENSE

Plaintiffs' claims are barred because GSK complied with applicable statutes and with the requirements and regulations of the Food and Drug Administration. See, e.g., U.S. Const. Art. VI, cl. 2.

TENTH DEFENSE

Each of the purported claims in Plaintiffs' Complaint may be barred by the applicable statute of limitations or repose.

ELEVENTH DEFENSE

Plaintiffs' claims are barred by the learned intermediary doctrine.

TWELFTH DEFENSE

Plaintiffs' purported claim for fraud and deceit must be dismissed because Plaintiffs failed to plead that claim with the requisite particularity, as required by Rule 9 of the Federal Rules of Civil Procedure.

THIRTEENTH DEFENSE

Plaintiffs unreasonably and inexcusably delayed the commencement and service of the above-entitled action to the prejudice of GSK and said action, therefore, is barred by the doctrine of laches.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part by the doctrines of waiver and/or estoppel.

FIFTEENTH DEFENSE

At all times material thereto, GSK's conduct conformed to the state of the art.

SIXTEENTH DEFENSE

Plaintiffs failed to give timely notice of any alleged breach of warranty, whether express or implied and said failure has prejudiced GSK.

SEVENTEENTH DEFENSE

Plaintiffs' claims for fraud and fraudulent misrepresentation are barred because the alleged representations and actions were not material, nor were likely to mislead consumers or healthcare providers acting reasonably under the circumstances. The alleged representations and actions did not, nor were likely to, affect Plaintiffs' decisions or conduct nor did they proximately or actually cause consumers, or Plaintiffs, to act differently.

EIGHTEENTH DEFENSE

Plaintiffs' claims are barred because GSK's alleged representations and conduct were in good faith and were not intended to deceive Plaintiffs.

NINETEENTH DEFENSE

GSK states that any and all warranties that may form a basis for Plaintiffs' claims for relief against GSK were adequately disclaimed or excluded by GSK.

TWENTIETH DEFENSE

Plaintiffs' alleged claims for breach of warranty are barred by lack of privity.

TWENTY-FIRST DEFENSE

GSK denies that it made any express or implied warranties.

TWENTY-SECOND DEFENSE

GSK pleads the application of Comment k to the Restatement (Second) of Torts § 402A and Restatement (Third) of Torts: Products Liability § 6. GSK provided adequate warning and complete warnings to Plaintiffs' prescribing physicians, and therefore, the product was not defective or unreasonably dangerous.

TWENTY-THIRD DEFENSE

Plaintiffs' alleged damages, if they were caused by the subject product, which GSK expressly denies, were caused by use of the product in contravention of warnings provided with it.

TWENTY-FOURTH DEFENSE

Plaintiffs' alleged damages were not caused by any failure to warn on the part of GSK.

TWENTY-FIFTH DEFENSE

Plaintiffs' alleged causes of action are barred, in whole or in part, by the lack of a defect under the consumer expectations test, which test GSK expressly contends is not applicable in this case.

TWENTY-SIXTH DEFENSE

Plaintiffs' alleged causes of action are barred because, based upon the scientific skill and knowledge at the time the subject product was distributed, the subject product was reasonably safe and the benefits of the product outweighed any associated risks.

TWENTY-SEVENTH DEFENSE

Plaintiffs' alleged damages, if they were caused by the product, which GSK expressly denies, were caused by an inherent characteristic of the product that could not be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

TWENTY-EIGHTH DEFENSE

Plaintiffs' alleged injuries or damages, if any, were the result of preexisting or subsequent conditions unrelated to Paxil.

TWENTY-NINTH DEFENSE

Plaintiffs' alleged injuries or damages, if any, may have been caused by an idiosyncratic reaction, without any negligence or failure on the part of GSK or any defect attributable to its product.

THIRTIETH DEFENSE

If Plaintiffs sustained injuries attributable to the use of the product at issue in this case, which allegations are expressly denied, the injuries were solely caused by and attributable to the unintended, unreasonable, and improper use, misuse, alteration, or modification which was made of said product.

THIRTY-FIRST DEFENSE

Plaintiffs may have failed to exercise ordinary care or reasonable care. If so, Plaintiffs' Complaint should be dismissed or their damages reduced under the doctrine of contributory negligence and/or comparative fault.

THIRTY-SECOND DEFENSE

GSK states that if Plaintiffs sustained any injuries or damages, which fact is specifically denied, and it is determined that said injuries or damages were caused, in whole or in part, by the act, omission, negligence, or fault of other persons or entities for whom GSK is not responsible, and such act, omission, negligence, or fault does not act as a complete bar to Plaintiffs' claims against GSK, then GSK is entitled to an apportionment of all such causal fault and a reduction of any award against it.

THIRTY-THIRD DEFENSE

The damages and injuries allegedly sustained by Plaintiffs, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

THIRTY-FOURTH DEFENSE

Plaintiffs' damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

THIRTY-FIFTH DEFENSE

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

THIRTY-SIXTH DEFENSE

Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

THIRTY-SEVENTH DEFENSE

GSK states that Plaintiffs' damages, if any, have been mitigated, in whole or in part, by reimbursement from collateral sources.

THIRTY-EIGHTH DEFENSE

To the extent that Plaintiffs claim damages for pain and suffering, such claims are barred because they violate GSK's right to due process and equal protection under the United States Constitution.

THIRTY-NINTH DEFENSE

Adequate and complete warnings and instructions were provided with the subject product, and the subject product was neither defective nor unreasonably dangerous when used according to label instruction.

FORTIETH DEFENSE

Plaintiffs' claim for breach of warranty is barred by the Uniform Commercial Code.

FORTY-FIRST DEFENSE

The imposition of punitive damages would violate GSK's equal protection and due process rights.

FORTY-SECOND DEFENSE

The imposition of punitive damages would violate GSK's right to due process under the Fifth and Fourteenth Amendments to the United States Constitution and GSK's right to equal protection under the Fourteenth Amendment to the United States Constitution.

FORTY-THIRD DEFENSE

Punitive damages are a punishment, a quasi-criminal sanction for which GSK has not been afforded the specific procedural safeguards prescribed in the Massachusetts Constitution and the Fifth and Sixth Amendments to the United States Constitution.

FORTY-FOURTH DEFENSE

With respect to Plaintiffs' demand for punitive damages, GSK specifically incorporates by reference all standards and/or limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408, 123 S.Ct. 1513 (U.S. 2003), together with all such standards applicable under Massachusetts or other law.

FORTY-FIFTH DEFENSE

Plaintiffs are not entitled to collect an award of punitive damages from GSK because an award of such damages could violate the excessive fines clauses of the United States Constitution.

FORTY-SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the economic loss rule.

FORTY-SEVENTH DEFENSE

GSK is not indebted or liable to Plaintiffs in any manner or amount whatsoever.

FORTY-EIGHTH DEFENSE

GSK had no actual or constructive notice of the alleged defects referred to in Plaintiffs' Complaint.

FORTY-NINTH DEFENSE

To the extent GSK had any obligations to Plaintiffs, such obligations have been fully, completely and properly performed in all respects.

FIFTIETH DEFENSE

Plaintiffs claims are barred in whole or in part for failure to comply adequately with statutory pre-litigation requirements.

FIFTY-FIRST DEFENSE

Plaintiffs did not rely on alleged warranties.

FIFTY-SECOND DEFENSE

Plaintiffs' claims are barred because they suffered no cognizable injury.

FIFTY-THIRD DEFENSE

Plaintiffs claims are barred to the extent their alleged damages are too speculative to be recoverable at law.

FIFTY-FOURTH DEFENSE

GSK hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery in this case or otherwise, and hereby reserves the right to amend this Answer to assert any such defenses.

FIFTY-FIFTH DEFENSE

To the extent not otherwise expressly and specifically admitted in this answer, GSK denies each and every allegation of Plaintiffs' Complaint.

FIFTY-SIXTH DEFENSE

To the extent that the law of any other State or Commonwealth applies to some or all of the Plaintiffs' purported claims, GSK incorporates and adopts on its behalf all defenses that would be available as a matter of law, statute or regulation under the law of such State or Commonwealth.

PRAYER FOR RELIEF

WHEREFORE, GSK prays that:

- (1) Plaintiffs take nothing by reason of Plaintiffs' Complaint;
- (2) Plaintiffs' Complaint against GSK be dismissed with prejudice in its entirety;
- (3) GSK recovers its costs; and
- (4) This Court award such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

GSK demands a jury trial.

Respectfully submitted,

SMITHKLINE BEECHAM
CORPORATION d/b/a
GLAXOSMITHKLINE

By its attorneys,



Ralph T. Lepore, III (BBO# 294420)
Deborah E. Barnard (BBO# 550654)
Elizabeth M. Mitchell (BBO# 638146)
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Dated: December 21, 2004.

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of December 2004, a true and correct copy of the forgoing was served upon the following by postage prepaid, U.S. Mail:

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